K003777

21 CFR §807.92
510(k) Summary of Safety and Effectiveness

December 5, 2000

Submitted by: Artemis Medical, Inc.
655 Mariners Island Blvd. Suite 303
San Mateo, CA 94404
Contact: Robin Bush
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Product: Caris™ Site Marker

Common Name: Implantable Staple, 21 CFR §878.4750

Intended Use

The Caris™ Site Marker is intended for use during an open surgical or percutaneous breast biopsy procedure to mark the biopsy site. The marker is visible on radiograph and ultrasound.

Device Description

The Caris Site Marker from Artemis Medical is a bioresorbable collagen plug embedded with a non-resorbable radiopaque marker. Using a syringe-like applicator, the Caris Site Marker is deployed into soft tissue during an open or percutaneous procedure to mark a surgical location for radiograph and ultrasound. The Caris Site Marker is intended to help relocate the breast tissue for any subsequent invervention or diagnosis. The collagen material slowly absorbs over a short period or time and the radiopaque marker is left behind as the permanent indicator of the biopsy site.

The Caris Site Marker is pre-packaged sterile in a disposable plunger-type applicator, ready for deployment into the biopsy site.

Substantial Equivalence

The Caris Site Marker has characteristics of more than one predicate device. The intended use as a biopsy site marker is similar to other devices used for this purpose. The collagen material is similar to surgical mesh and membrane materials that are implanted as absorbable materials in soft tissue surgery.

The Caris Site Marker from Artemis Medical is substantially equivalent to the following biopsy markers:

- Gel Mark Breast Biopsy Marker by SenoRx, Inc. (#K000060)
- MicroMark Clip by Biopsys Medical (Ethicon EndoSurgery) (#K970817)
- VMI Biopsy Marker System by Vivant Medical (#K000278)
- Auto Suture Site Marker Clip by United States Surgical Corp. (#K983400)

These devices each are intended for the radiographic marking of soft tissue during open or percutaneous breast biopsy procedures. The markers are visible radiographically. The markers are placed into the site using an applicator.

Technological Characteristics

Caris Site Marker and its predicates have similar technological characteristics. These devices incorporate a metal material which serves as the radiopaque marker to identify the site of the biopsy.

The Caris Site Marker consists primarily of Type I collagen derived from bovine hide. It is one of the purest forms of collagen. The Caris Site Mark embeds a small piece of radiopaque metal into the center of the collagen foam. Once the of collagen resorbs, the radiopaque mark is left behind at the site of the breast biopsy.

Each of the predicate devices identified above contain a metal wire made of titanium or stainless steel. Additionally, the Gel Mark Biopsy Marker from SenoRx (#K000060) contains a resorbable material (gelatin) with metal marker. Once the gelatin resorbs, the metal becomes the permanent marker.

The Caris Site Marker does not introduce new technological issues.

Performance Data

Performance data have been performed to assure the device contains functional characteristics of a tissue site marker. A palpability test of the mark immediately post implantation in an animal model was conducted to determine the palpability of the mark. A hydration study of the Caris Site Marker was conducted to assess the expansion properties of the biopsy marker when in contact with isotonic saline at body temperature. Ultrasound and radiographic imaging have confirmed the visibility of the Caris Site Marker during simulated use and imaging in porcine studies. Analytical testing, biochemical characterization, biocompatibility tests (according to ISO 10993), and a viral inactivation study have also been completed on the raw materials and/or final product.

Summary

The Caris Site Marker is substantially equivalent in intended use, overall design, material, and characteristics to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2001

Ms. Robin Bush
Vice President, Regulatory
and Clinical Affairs
Artemis Medical, Inc.
655 Mariners Island Boulevard
Suite 303
San Mateo, California 94404

Re: K003777
Trade Name: Caris™ Site Marker
Regulatory Class: II
Product Code: FZP
Dated: December 5, 2000
Received: December 7, 2000

Dear Ms. Bush:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K003777

Device Name:

Caris™ Site Marker

Indication for Use:

The Caris™ Site Marker is intended for use during an open surgical or percutaneous breast biopsy procedure to mark the biopsy site.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K003777